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ORIGINAL ARTICLE • HIP - TRAUMA

Femoral offset loss and internal arch restoration defect are correlated with intramedullary nail cut-out complications after pertrochanteric fractures: a case–control study

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Abstract
Background and purpose In a previous study, we investigated the link between the femoral offset (FO) loss by trochanteric impaction (TI) and cut-out complication occurrence after pertrochanteric fractures. Three major factors are likely to drive to failure after intramedullary nailing (IN): fracture stability, reduction quality and osteosynthesis quality. We wanted to investigate the quality of the fracture reduction through the TI and the neck-shaft angle (NSA) measurement and correlate these parameters with the risk of mechanical failure occurrence.
Materials and methods It was a retrospective multicentric one case–one control match design study with age and gender randomization. The cases presented a mechanical failure of nailing: $TI = 1 - \frac{FO_{fractured}}{FO_{healthy}}$ in percentage. Femoral rotation was taken into account, and all TI were rotation-corrected ($TI_{corrected}$). Rotation-corrected neck-shaft angles ($NSA_{corrected}$) were calculated. The neck-shaft angle gap between the fractured and the healthy sides (NSA_{gap}) was a ratio: $NSA_{gap} = 1 - \frac{NSA_{corrected}}{NSA_{healthy}}$ in percentage. The tip–apex distance (TAD) was measured. Absolute values of $TI_{corrected}$ and NSA_{gap} were analyzed.
Results Twenty-one cases and 21 controls were examined. The average $TI_{corrected}$ rate was 30% for the cases and 11% for the controls ($p = 0.007$). A 13% $TI_{corrected}$ threshold had maximum specificity and sensitivity, equal to 71%. The average TAD was 27 mm for cases and 19 mm for controls ($p = 0.004$). The average NSA_{gap} rate was 7% for the case group and 4% for the control group ($p = 0.009$). The areas under the ROC curves for $TI_{corrected}$, TAD and NSA_{gap} were 0.73, 0.73 and 0.66, respectively.
Interpretation Closed reduction and exclusive implantation of IN do not seem optimal in case of FO or NSA restoration failure after pertrochanteric fractures.
Level of evidence Level III, case–control study.

Keywords Pertrochanteric fracture · Intramedullary nail · Mechanical complication · Cut-out · Femoral offset · Hip rotation · Tip–apex distance · Neck-shaft angle

Introduction

Pertrochanteric fractures (PF) account for 40% of all upper femur fractures. Their prevalence has been increasing, with estimated 35,000 cases per year in France. Because of the increase of inhabitants in the geriatric age group, the upper femoral fracture incidence decreases over time in France [1]. There are two main device types indicated for such fractures: screw-plates and intramedullary nails (IN). Mechanical failure incidence after intramedullary nailing varies between 1.8 and 16.5% in the literature [2–4].

The tip–apex distance measurement is the most commonly used for assessing the disassembly risk after IN [3].

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It is possible to identify three parameters involved in the risk of disassembly: fracture stability [5, 6], reduction quality [3, 5, 7, 8] and osteosynthesis quality [3, 7, 9, 10].

Among these parameters, some authors distinguish between those which can be modifiable and those which cannot be modified [11]. The initial stability of the fracture is an unmodifiable factor. The TAD and the positioning of the cervical screw in the cervix are two questionable parameters: They can be a non-modifiable once the intervention is over. They can also be correlated with the fracture reduction quality and therefore be modified during the fracture reduction procedure. We think that the quality of the fracture reduction is the cornerstone when analyzing the mechanical failures. However, the reduction is a difficult parameter to evaluate objectively. The neck-shaft angle (NSA) is an identified parameter that reflects the quality of the reduction and is correlated with the risk of disassembly [11, 12].

In a previous study, we investigated the link between the loss of femoral offset (FO) by trochanteric impaction (TI) and cervical screw cut-out complication occurrence after dynamic hip screw (DHS) [13]. TI evaluation was our objective approach to assess fracture stability and its comminution without recourse to classifications. This parameter can also be used to assess the quality of the fracture reduction during the surgical procedure. We found out that a strong TI, manifesting itself as a strong FO loss, was strongly predictive of disassembly occurrence. Likewise, our findings suggested that DHS were probably not a good surgical approach for highly impacted PF.

Analyzing NSA and the FO is complex because of the hip rotations. Indeed, these two parameters depend on rotations [14]. Hyper-internal rotation may be responsible for underestimating these parameters. Therefore, it is required to have a precise assessment of the hip rotation when measuring NSA and FO. This is possible by measuring the projected angle of the nail [14, 15].

We can identify two main issues, which will be the primary and secondary objectives of this study. The first question is to assess the extend to which the failure of FO restoration is a risk factor for mechanical failure.

The second question is to determine what is the performance of each of the prognostic parameters that we have just mentioned as well as their intercorrelation.

Materials and methods

The sample

A retrospective multicentric case–control study was conducted. All patients were treated between January 2008 and January 2018. The 21 cases were patients who received IN treatment (20 Gamma nail®, Stryker, 1 PFNA® Synthes) for their PF and who subsequently presented a mechanical complication such as cervical screw cut-out (Fig. 1), head perforation by cervical screw, pseudarthrosis, warranting a surgical revision. The 21 controls were patients who also received IN treatment for their PF (20 Gamma, 1 PFNA) but did not subsequently suffer from any mechanical complication over the 2 years following their surgical treatment. As in the case group, they were randomly selected over a similar period. A one case–one control match design was used, and the patients were randomized by age and gender. The patients with documented second fracture after osteosynthesis, high kinetic mechanism, pathological fracture and subtrochanteric fracture were excluded from the study. The patients suffering from a contralateral femoral arthroplasty were excluded from the control group.

Primary endpoint

TI quantification represented the study primary endpoint. The measurement was taken on a front pelvis radiograph immediately after surgery. FO was the shortest distance between the center of the femoral head and the femoral shaft axis (Fig. 2). FO on the operated hip was compared to the contralateral one. $TI = 1 - \frac{FO_{fractured}}{FO_{healthy}}$. This ratio was expressed as a percentage.

Femoral rotation and neck-shaft anteversion may result in a measurement gap between the projected FO and the actual FO. We corrected all the projected FO values for femoral rotation. We estimated the femoral rotation by measuring the projected Gamma angle γP of the nails, using the technique described by Lechler et al. [14]. The Gamma angle of the nails is defined by the constructor. For example, the real Gamma angle (γR) for a 125° Gamma nail is 55°. Also, a

Fig. 1 Gamma nail cervical screw cut-out

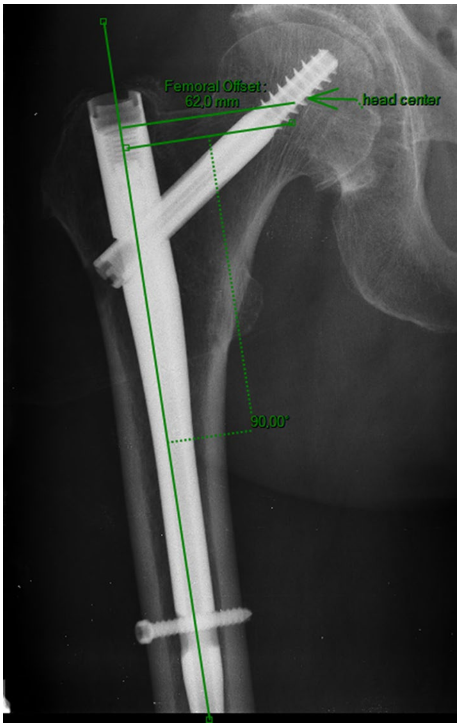


Fig. 2 FO calculation: the shortest distance between the center of the femoral head and the femoral shaft axis

difference between γP and γP means that there is a hip rotation (Fig. 3). The quantification of hip rotation is determined by a table provided by Lechler et al., knowing the γR of the nail and the measuring γP. For example (Fig. 4), if we measure $\gamma P = 35°$ in case of a 125° Gamma nail ($\gamma R = 55°$), we can estimate that internal hip rotation (IHR) = 60°, according to Lechler's table. This same table gives a rotation correction factor (RCF) with which it is possible to correct the projected $FO_{projected}$ according to the hip rotation: $FO_{corrected} = FO_{projected} \times RCF$. Still in the same example, $\gamma P = 35°$ with a 125° Gamma nail, IHR = 60°, RCF = 2 and $FO_{corrected} = FO_{projected} \times 2$. Corrected TI ($TI_{corrected}$) was then calculated: $TI_{corrected} = 1 - \frac{FO_{corrected}}{FO_{healthy}} = 1 - \frac{FO_{projected} \times RCF}{FO_{healthy}}$.

We noticed that FO could be increased when compared to the healthy hip (over-corrected FO), resulting in $TI < 0$ (Fig. 5). This is why we used TIcor absolute value which is called $|TI_{corrected}|$.

The correlation between the disassembly occurrence and $|TI_{corrected}|$ was studied through progressive impaction stages, from 0% impaction rate to over 30% impaction rate. Specificity and sensitivity variation was computed for each impaction stage, which allowed to create a receiver operating characteristic curve (ROC) in order to assess TI measurement performance. Calculating the area under the curve should allow to interpret the results of a ROC curve. Any area exceeding 0.5 shows that the $|TI_{corrected}|$/disassembly correlation was not a coincidence.

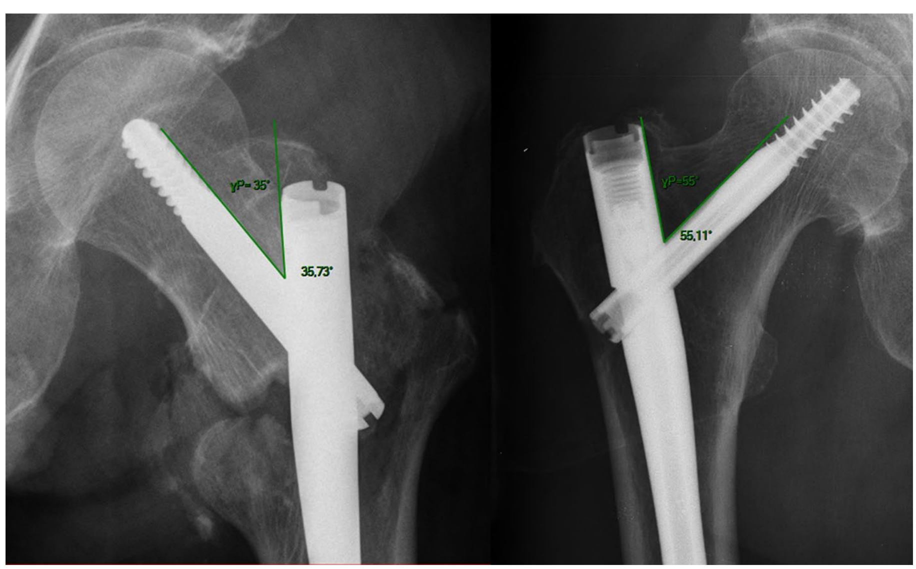
Secondary endpoints

Fractures were classified according to the AO (31A1 1-3, 31A2 1-3, 31A3 1-3) and Ender classifications. Ender types 4 and 5 fractures are characterized by significant trochanteric spongy bone impaction [6].

Osteosynthesis quality was assessed through tip–apex distance (TAD) [3] measurement on front and lateral hip radiographs. A TAD specificity/sensitivity study was carried out, defining 1-mm stages and a ROC curve.

Screw positioning in the femoral neck was assessed, basing on the nine Cleveland and Kyle zones [3, 16, 17]. The

Fig. 3 Calculation of the projected Gamma angles γP. On the left, $\gamma P = 35$; it is a 125° Gamma nail; normal $\gamma = 55°$; according to Lechler's table, there is 45° hip rotation. On the right, $\gamma P = 55$; it is a 125° Gamma nail; normal $\gamma = 55°$, so there is no hip rotation



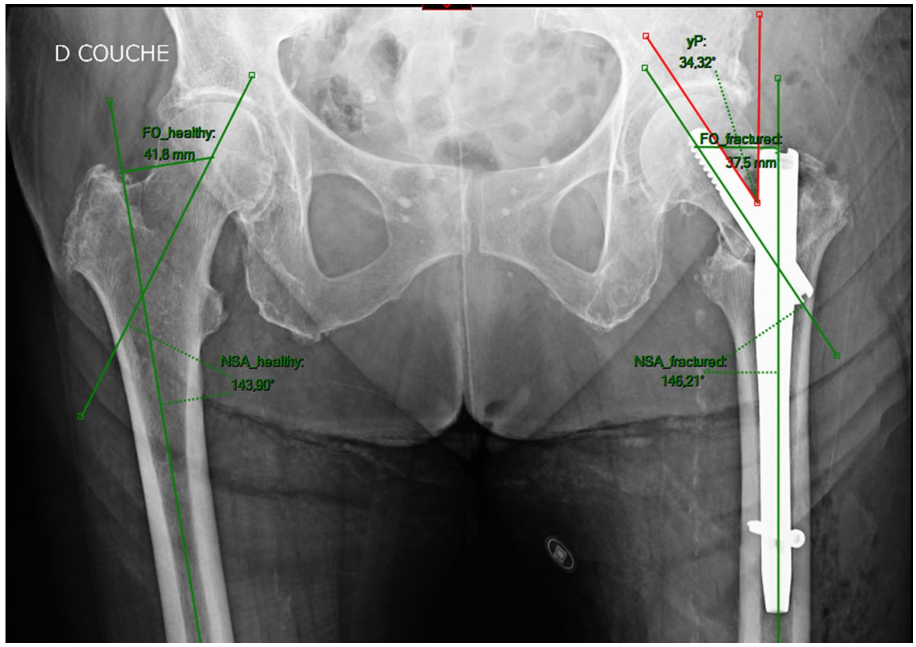


Fig. 4 In this case, $FO_{projected}$ in the fractured side seemed to be equal to that in the healthy side (37 mm vs. 42 mm) and TI = 12%. However, the γP angle (in red) is equal to 34°. According to the Lechler's table, there is 60° internal hip rotation and the rotation correction factor (RCF) = 2. The corrected FO ($FO_{corrected}$) was actually increased in comparison with that in the healthy side: $FO_{corrected} = RCF \times FO_{projected} = 2 \times FO_{projected} = 2 \times 37 = 74$ mm. So $|TI_{corrected}| = 76\%$ (color figure online)

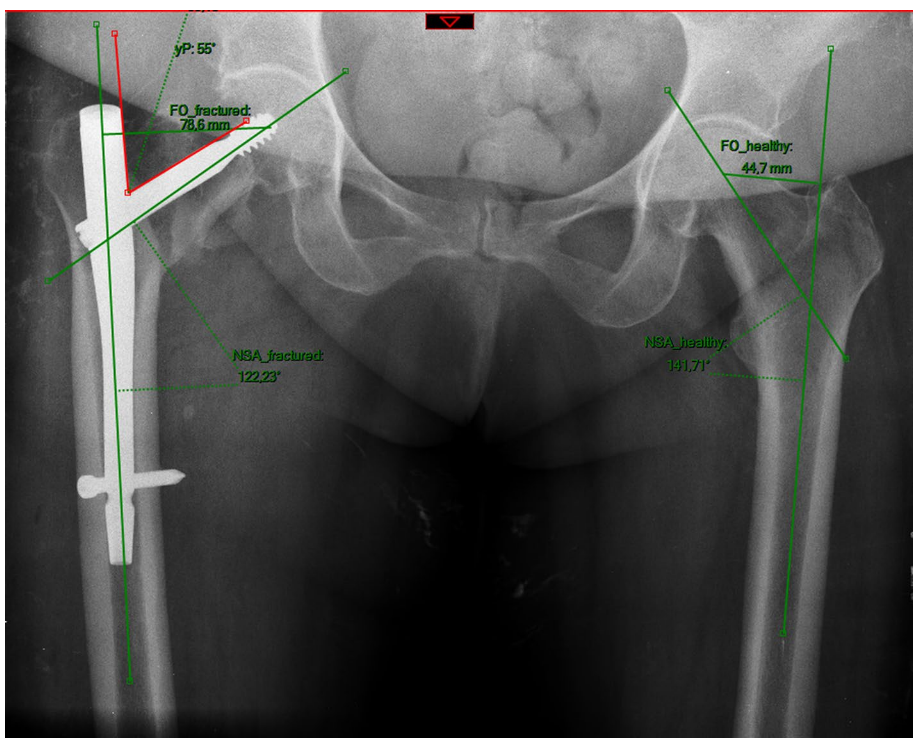


Fig. 5 In this case, there was no internal hip rotation: $\gamma P = 55°$ (in red). $FO_{projected} = FO_{corrected}$ so $TI = TI_{corrected}$. FO in the fractured side was much more important than that in the healthy side. This was associated with a poor NSA restitution, in great valgus (color figure online)

disassembly risk zones were the superior ones, along with the inferior/posterior zone.

The internal arch restitution was calculated through the frontal neck-shaft angles (NSAs) on both hips. The NSA measurement on the fractured side was rotation-corrected ($NSA_{corrected}$) using γP and γR. The more the IHR was increasing, the more the projected NSA ($NSA_{projected}$) was increasing, and the less the $NSA_{corrected}$ was decreasing. Fracture reduction is supposed to be achieved once the NSAs are equivalent on both sides. The measurement of NSA gap (NSA_{gap}) between both sides was established with a NSA ratio: $NSA_{gap} = 1 - \frac{NSA_{corrected}}{NSA_{healthy}}$ expressed as a percentage. A

NSA_{gap} specificity/sensibility study was carried out, using 1% stages of absolute NSA_{gap} values ($|NSA_{gap}|$) and a ROC curve.

Postoperative weight-bearing prescription and delays before disassembly occurrence were also reported.

Statistical calculations

Data management and analyses were carried out on R software (version 3.4.3, 2017-11-30). Primary alpha risk was 0.05. Wilcoxon tests were used to compare averages and Fisher tests were used for proportions. The TAD – $|TI_{corrected}|$ and $|NSA_{gap}| - |TI_{corrected}|$ correlations were assessed using Pearson correlation tests. A multiple logistic regression was performed to assess the disassembly risk according to $|TI_{corrected}|$, $|NSA_{gap}|$, screw positioning and TAD.

The ethics

It was a retrospective study that did not involve the human person. It was not necessary to seek an opinion from an ethics committee. The personal data of the patients were collected in a completely anonymous way.

Results

The sample

There were 18 women (85%) in each group. Mean age was 84 years (median: 88 years, minimum: 65 years, maximum: 94 years) in each group.

Primary endpoint

The overall $FO_{projected}$ average on the fractured side was 49 mm (minimum: 38 mm, maximum: 78 mm). The overall $FO_{corrected}$ average was 57 mm (minimum: 40 mm, maximum: 115 mm). The difference between $FO_{projected}$ and $FO_{corrected}$ was significative ($p = 0.004$). The overall FO average on the healthy side was 49 mm (minimum 40 mm, maximum 61 mm).

The average TI rate was −0.5% for the cases [minimum: −65%, maximum 28%, 95% CI (−11%; 10%)] and 0.5% for the controls [minimum: −22%, maximum: 30%, 95% CI (−5%; 6%)].

The average $|TI_{corrected}|$ rate was 31% for the cases [95% CI (17%; 45%)] and 11% for the controls [95% CI (7%; 15%)], $p = 0.007$.

The area under the ROC curve was 0.72 for $|TI_{corrected}|$ measurement (Fig. 6).

Figure 7 shows the sensitivity and specificity tied to each $|TI_{corrected}|$ stage. The higher the $|TI_{corrected}|$ rate was, the more the specificity was increasing, and the more the sensitivity was decreasing. A 13% $|TI_{corrected}|$ threshold was tied to both maximum specificity and sensitivity rates, equal to 71%.

A $|TI_{corrected}|$ rate higher than 13% was significantly correlated with disassembly over-risk, with an odds ratio = 6, 95% CI (2; 27), $p = 0.007$.

Secondary endpoints

The average TAD was 27 mm for cases [95% CI (22 mm; 32 mm)] and 19 mm for controls [95% CI (16 mm; 22 mm)], $p = 0.004$. The area under the ROC curve was 0.73 (Fig. 6). TAD and $|TI_{corrected}|$ measurements had a 0.58 Pearson correlation coefficient ($p < 10^{-5}$).

Twelve case patients had a screw positioning in a zone at high risk of disassembly, against 6 patients in the control group. This was not significant.

The average $|NSA_{gap}|$ rate was 7% for the case group [95% CI (5%; 10%)] and 4% for the control group [95% CI (3%; 5%)], $p = 0.009$. The area under the ROC curve was 0.66 for $|NSA_{gap}|$ (Fig. 6). Figure 8 shows the sensitivity and specificity tied to each $|NSA_{gap}|$ stage. The higher the $|NSA_{gap}|$ rate was, the more the specificity was increasing and sensitivity decreasing. A 4% $|NSA_{gap}|$ threshold was tied to both maximum specificity and sensitivity rates, equal to 70%. A $|NSA_{gap}|$ rate higher than 4% was significantly correlated with disassembly over-risk, with an odds ratio = 6, 95% CI (2; 30), $p = 0.006$.

$|NSA_{gap}|$ and $|TI_{corrected}|$ measurements had a 0.60 Pearson correlation coefficient ($p < 10^{-5}$).

We did not find any significant difference between the two groups regarding fracture classifications. Thirteen cases (62%) versus 7 controls (33%) had A2-type fractures (multifragmentary pertrochanteric fractures, lateral wall incompetent). This difference was not significant either.

The lesser trochanter fracture rate was strictly the same within the two groups: 50%. All the patients in the case and control groups had postoperative weight-bearing authorization.

Among the multiple logistic regression, including $|TI_{corrected}|$, $|NSA_{gap}|$, TAD and screw positioning, only $|TI_{corrected}|$ measurement has reached a significant gap between case and control groups. A $|TI_{corrected}|$ rate higher than 13% was significantly correlated with disassembly over-risk, with an odds ratio = 4.6, 95% CI (0; 23), $p = 0.05$.

Figure 9 shows a Kaplan–Meier curve which indicates the time elapsing between cut-out occurrence and surgery. Failures occurred with a median 47-day delay. There was not any correlation between $|TI_{corrected}|$ and time elapsed between surgery and cut-out.

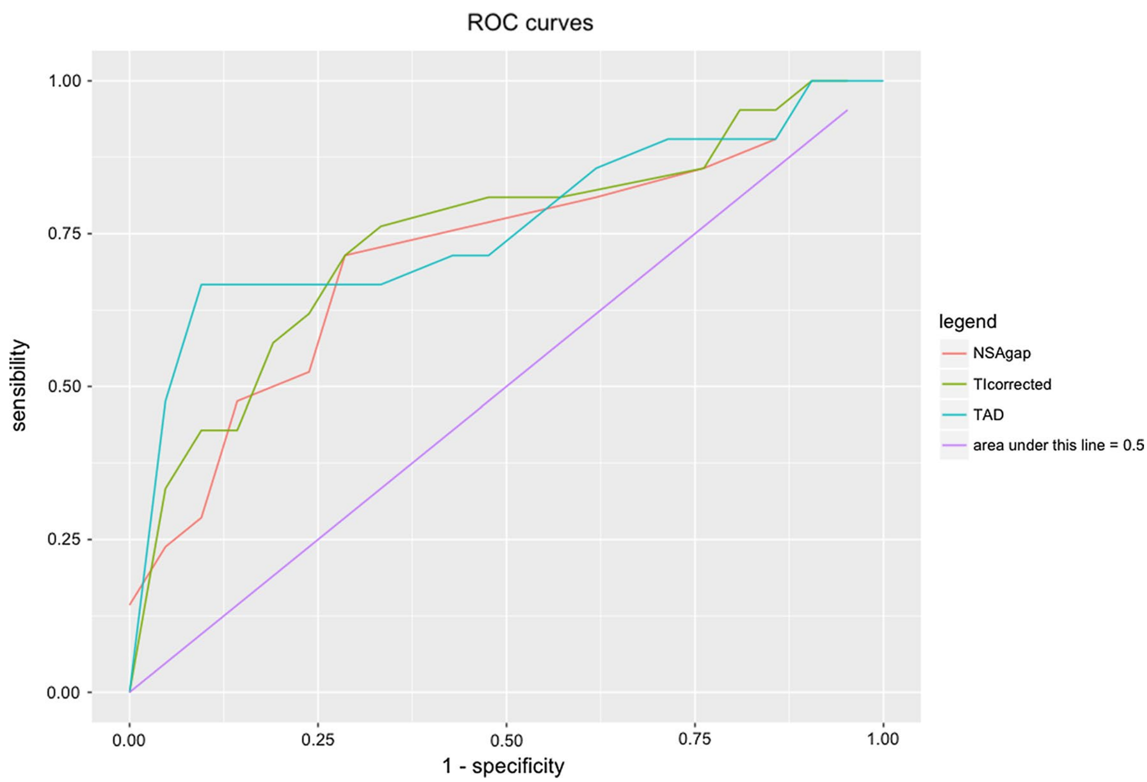


Fig. 6 ROC curves associated with $|TI_{corrected}|$, $|NSA_{gap}|$ and TAD measurements

Discussion

Our results reveal that increased disassembly risk is strongly correlated with three factors: failure of FO restoration, bad NSA restoration and poor TAD. For these three parameters, the areas under the ROC curves were equivalent, which suggested equivalent predictive value. Moreover, in our multivariate analysis, only NSA restoration emerged as a determining factor for disassembly. Besides, these three parameters were strongly intercorrelated.

We already analyzed FO restoration as a parameter in a previous study, while surveying DHS cut-out occurrence after pertrochanteric fractures. In this previous series [13], FO loss was strongly correlated with disassembly risk. In this present series, FO could be increased, up to 116%. This was also correlated with disassembly over-risk (Fig. 5). The offset increase can be explicated by the strong trochanteric comminution [6, 8] and the proximal 15.5 mm diameter of the Gamma nail [18]. Another substantial difference compared to DHS is that the disassembly occurrence delay was 20 days longer in this IN series than in our DHS series.

FO restoration is an easily achievable measurement based on an antero-posterior pelvic radiographic view, whatever the calibration factor. The correction of measurements using the projected angle of the nail is indispensable to take into account the hip rotations. Our corrected FO values were similar to those observed by Buecking et al. The correction makes it possible to detect the "true/false corrections" of the FO. In this situation, the reduction seems good when in fact it is not (Fig. 4). To our knowledge, the link between FO and the cut-out risk has never been established after IN. We have identified two studies linking FO restoration and functional recovery [15, 19]. Notably, Buecking [15] revealed lower Barthel and Harris scores for patients with excessive FO correction.

The NSA is the direct reflection of the restoration of the internal arch. Its restoration is a well-identified parameter in the literature but is still debated [10]. PF reduction techniques are now well codified. Many authors agree that fracture reduction should restore the NSA angle and also that a small valgus remains acceptable [5, 7–9, 19, 20]. In our series, extreme gap in NSA measurement, taking the healthy hip side as a benchmark, was highly correlated with failures, whether in varus or valgus. We identified a 5% threshold for NSA differential measurement. Besides, NSA and TI were strongly correlated, which can be explained by a trigonometric law: $\tan(180° - \text{NSA}) = \frac{\text{FO}}{\text{neck and head lenght}}$ (Fig. 10).

The definition of fracture instability may differ, depending on the varying views of the authors and the classifications read. Although there was no significant difference

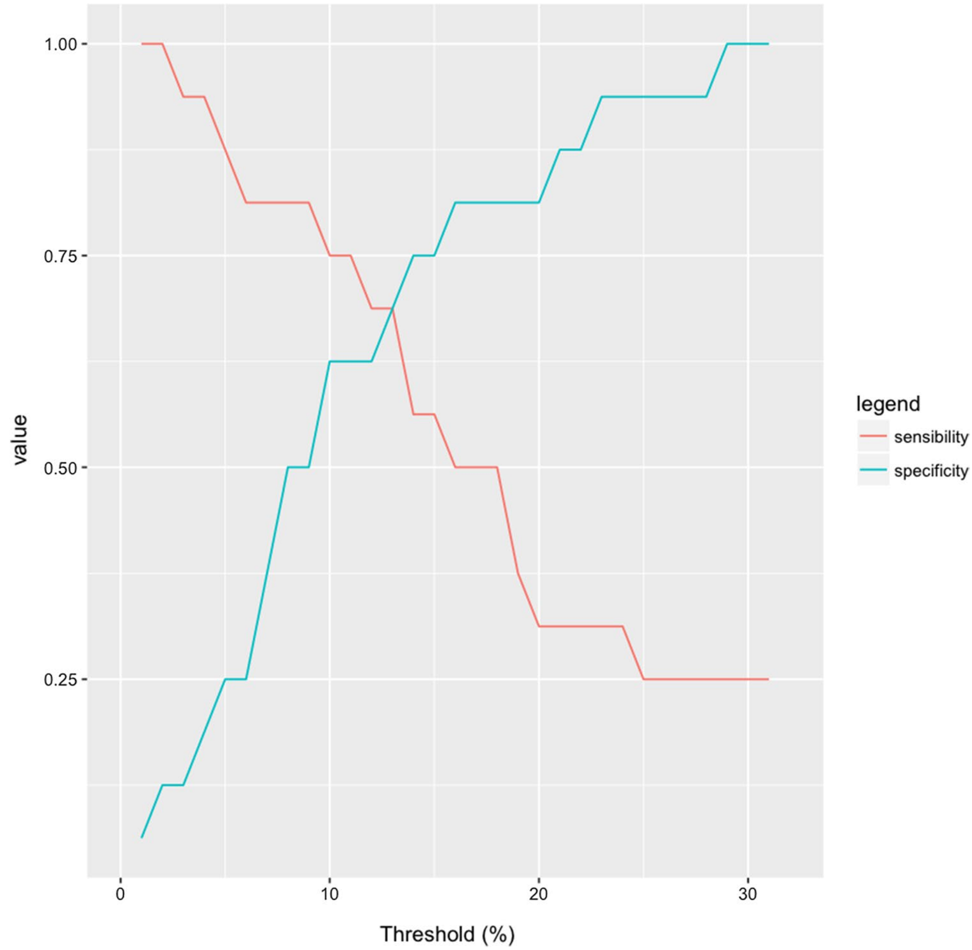


Fig. 7 Sensibility and specificity of $|TI_{corrected}|$

in fracture classifications between cases and controls, patients with mechanical failure had 2 times more comminuted fractures (A2). We retrospectively investigated the sensitivity and specificity of the classifications to predict disassembly at 60–70% [21–23]. The major shortcoming of classifications remains their low reproducibility, around 0.35 in the literature [24, 25].

The disassembly risk may be also evaluated by measuring the device position accuracy. The best-known technic is the TAD, as introduced by Baumgaertner et al. [3]. A failure risk may exist for a TAD value exceeding 25 mm. Our results were concordant, and we found that TAD was a good predictor, with an area under the ROC curve equivalent to the ones found under the NSA and TI curves. Our ROC curve was also close to that found by De Bruijn et al. [7].

The strong correlation between TAD and TI can be explained by the trochanteric bone destruction responsible for reduction difficulties than device implantation. Other material-related measures are described in the literature, such as the Parker index which we did not calculate, as well as the cervical screw position according to the Cleveland and Kyle 9 zones [3, 16, 17]. This last parameter did not show any significant difference in our study, probably due to a lack of statistical power.

There are other non-mechanical parameters that can explain the cut-out occurrence. Among them, there are bone fragility and osteoporosis. This is a parameter that is still mentioned, but up to date and to our knowledge, there is no significant evidence with bone densitometry [12, 26].

The ultimate goal of our global approach is to allow the identification of PF at high disassembly risk as early as possible, to promptly adapt the therapeutic management. Three key moments in the management of pertrochanteric fractures can be described. The first one is when fracture occurs. Helping classifications, the fracture foreseeable instability can be identified. The risk at this stage is the lack of inter-user reproducibility. The second moment is during fracture closed reduction. When the fracture presents either a FO or NSA restoration defect, osteosynthesis by IN or screw plate should not be started. These types of fracture should be identified, in order to receive a specific treatment like an open reduction. If not sufficient, some authors have reported good functional and mechanical results after the treatment of PF by hip arthroplasty [27, 28]. Other authors have described the cement supplementation technic, yet to date there is no

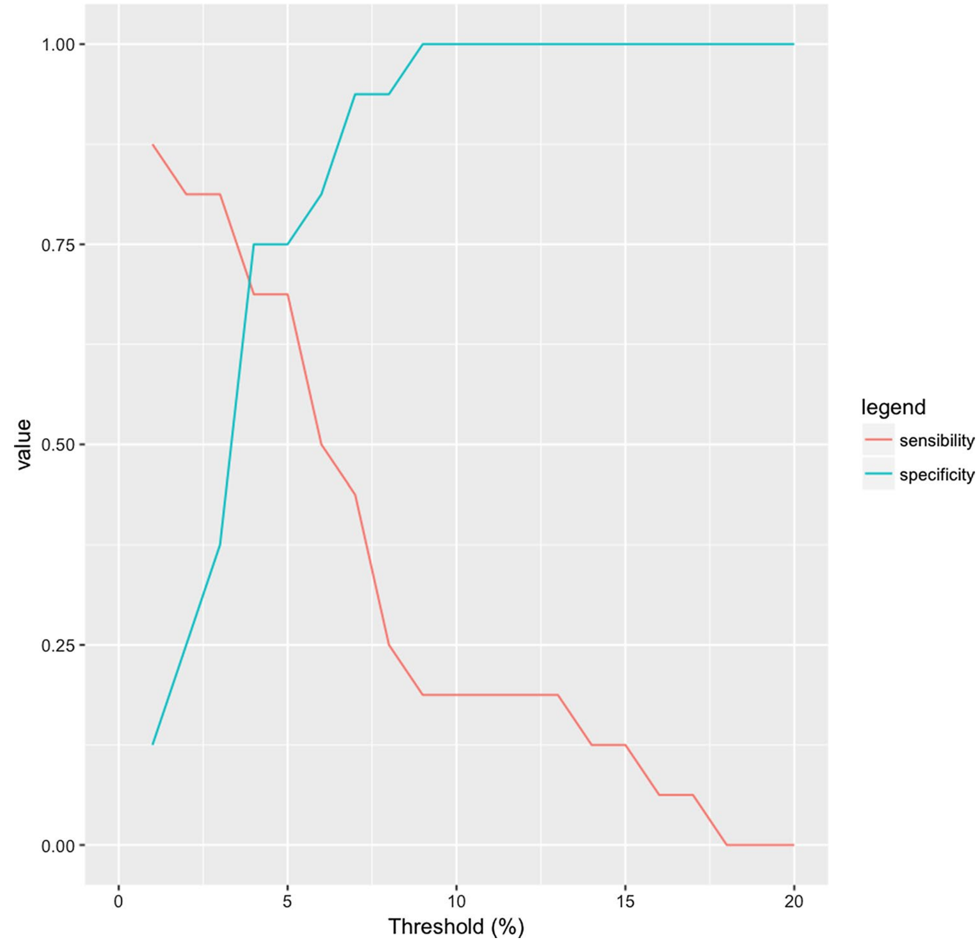


Fig. 8 Sensibility and specificity of $|NSA_{gap}|$

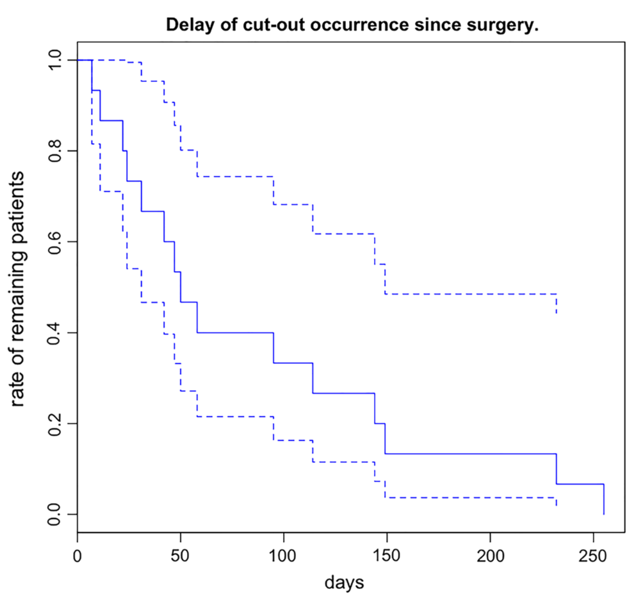


Fig. 9 Delay of cut-out occurrence since surgery

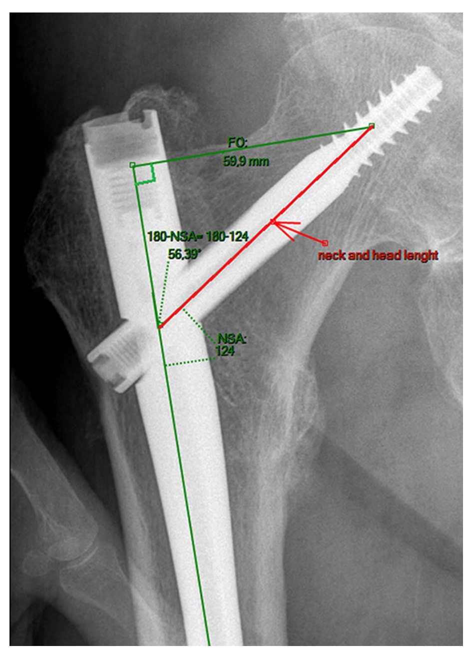


Fig. 10 NSA and TI correlation explained by a trigonometric law: $\tan(180° - \text{NSA}) = \frac{\text{FO}}{\text{neck and head lenght}}$

evidence in favor of its mechanical efficacy [29–32]. Likewise, weight-bearing interdiction should be specifically studied for the patients at high risk of postoperative failure. The third key moment is after the osteosynthesis. A good implant position is required, but this depends to the previous parameters. At this stage, it seems that there only remains the weight-bearing interdiction in order to avoid failure occurrence. To date, it is difficult to find evidence that weight-bearing modulation is efficient.

Our study has notable limitations. The main one is the small number of patients involved, which tempers our views in this study as well as its power. We encountered matching difficulties when trying to match each case to more than one control. To ensure the absence of mechanical failure, all control patients had to be followed-up for two years at least. Due to a high patient-loss rate, there were few candidates for the control group and we resolved to keep a one case–one control match design. The main risk associated with this was to ignore mechanical complications.

Conclusion

FO and NSA restauration seemed to be strongly correlated with disassembly over-risk. FO and NSA restauration accuracy were correlated with TAD outcomes. We recommend a systematic assessment of contralateral FO and NSA during the closed reduction procedure, so as to detect non-optimal reductions. In these latter cases, closed reduction and exclusive implantation of IN do not seem optimal. Weight-bearing prohibition is another possibility to explore. The detection of the "true/false fracture reductions" measuring the projected angles γP should be systematic. This makes it possible to estimate the IHR and to correct the measurements.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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